

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT**

UCB, INC., UCB PHARMA GMBH, and LTS))	
LOHMANN THERAPIE-SYSTEME AG))	
)	
Plaintiffs/Counterclaim))	
Defendants,))	
)	
v.))	Case No. 2:22-cv-00216-cr
)	
MYLAN TECHNOLOGIES INC.,))	
)	
Defendant/Counterclaim))	
Plaintiff.))	

PLAINTIFFS' ANSWER TO MYLAN TECHNOLOGIES INC.'S COUNTERCLAIMS

Plaintiffs/Counterclaim Defendants UCB, Inc., UCB Pharma GmbH (collectively, “UCB”), and LTS Lohmann Therapie-Systeme AG (“LTS”) (collectively, “Plaintiffs” or “Counterclaim Defendants”), by their undersigned attorneys, hereby answer the Counterclaims filed on February 13, 2023 (Dkt. 17) by Defendant/Counterclaim Plaintiff Mylan Technologies Inc. (“MTI”) as follows:

MTI'S ANSWER AND AFFIRMATIVE DEFENSES

Paragraphs 1–139 and the Affirmative Defenses of the Answer (Dkt. 17) filed by MTI are not part of MTI’s Counterclaims and require no response by Plaintiffs.

ANSWER TO MTI'S COUNTERCLAIMS

Plaintiffs deny all allegations in MTI’s Counterclaims except as expressly admitted below.

PARTIES

1. MTI is a West Virginia corporation with a principal place of business at 110 Lake St., St. Albans, VT.

ANSWER: Upon information and belief, admitted.

2. Upon information and belief, UCB, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1950 Lake Park Drive, Smyrna, Georgia 30080.

ANSWER: Admitted.

3. Upon information and belief, UCB Pharma GmbH (“UCB Pharma”) is a corporation organized and existing under the laws of the Federal Republic of Germany, having an office and place of business at Alfred Nobel Strasse 10, 40789 Monheim, Germany.

ANSWER: Admitted.

4. Upon information and belief, LTS Lohmann Therapie-Systeme AG (“LTS”) is a corporation organized and existing under the laws of the Federal Republic of Germany, having an office and place of business at Lohmannstrasse 2, 56626 Andernach, Germany.

ANSWER: Admitted.

JURISDICTION AND VENUE

5. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and contract law.

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no response is required. To the extent that an answer may be required, Plaintiffs admit that Counts I through VIII purport to raise requests for declaratory judgments or judicial declarations as to non-infringement and invalidity with respect to the Patent Laws of the United States, that Counts I through X contain “Declaratory Judgment” in the title of each count, and that Counts I through IX purport to seek either a declaratory judgment or judicial declaration. Plaintiffs admit that Count XI is entitled “Breach of Covenant Not to Sue,” although the Count does not state the basis for the Court’s subject matter jurisdiction over the count. To the extent Paragraph 5 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

6. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no response is required. To the extent that an answer is required, for the purposes of this action only, Plaintiffs

admit that the Court has subject matter jurisdiction pursuant to, *inter alia*, 28 U.S.C. §§ 1331 and 1338(a) to adjudicate Counts I through VIII within the context of Counts I through VIII of Plaintiffs' Complaint. Regarding Counts IX through XII, Plaintiffs deny that Defendant has adequately pleaded subject matter jurisdiction for those counts and the foregoing allegations are thus denied with respect to those counts. To the extent Paragraph 6 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

7. The Court has personal jurisdiction over Counterclaim Defendants at least because Counterclaim Defendants commenced and continue to maintain this action against MTI in this judicial district.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no response is required. To the extent that an answer is required, Plaintiffs admit that they have sued MTI in this judicial district in the present action. For purposes of this action only, Plaintiffs do not contest personal jurisdiction in this judicial district with respect to MTI's Counterclaims. To the extent Paragraph 7 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) at least because Counterclaim Defendants commenced and continue to maintain this action against MTI in this judicial district.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no response is required. To the extent that an answer is required, Plaintiffs admit that they have sued MTI in this judicial district in the present action. For purposes of this action only, Plaintiffs do not contest venue in this judicial district with respect to MTI's Counterclaims. To the extent Paragraph 8 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

FACTUAL BACKGROUND

9. Upon information and belief, on August 21, 2012, the USPTO issued the '979 Patent, entitled "Transdermal Delivery System for the Administration of Rotigotine." Upon information and belief, UCB Pharma is the assignee of the '979 patent. A copy of the '979 patent was attached to Counterclaim Defendants' Complaint as Exhibit A.

ANSWER: Admitted.

10. Upon information and belief, on August 21, 2012, the USPTO issued the '980 Patent, entitled "Transdermal Delivery System." Upon information and belief, UCB Pharma is the assignee of the '980 patent. A copy of the '980 patent was attached to Counterclaim Defendants' Complaint as Exhibit B.

ANSWER: Admitted.

11. Upon information and belief, on November 20, 2018, the USPTO issued the '589 Patent, entitled "Polyvinylpyrrolidone for the Stabilization of a Solid Dispersion of the Non-Crystalline Form of Rotigotine." Upon information and belief, UCB Pharma and LTS are the assignees of the '589 patent. A copy of the '589 patent was attached to Counterclaim Defendants' Complaint as Exhibit C.

ANSWER: Admitted.

12. Upon information and belief, on July 16, 2019, the USPTO issued the '174 Patent, entitled "Polyvinylpyrrolidone for the Stabilization of a Solid Dispersion of the Non- Crystalline Form of Rotigotine." Upon information and belief, UCB Pharma is the assignee of the '174 patent. A copy of the '174 patent was attached to Counterclaim Defendants' Complaint as Exhibit D.

ANSWER: Admitted.

13. Upon information and belief, UCB, Inc. is indicated in the records of the FDA as the holder of NDA No. 021829 for Neupro® rotigotine transdermal formulations (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours).

ANSWER: Admitted.

14. The '979, '980, '589 and '174 patents, as well as U.S. Patent Nos. 8,617,591 ("the '591 patent") and 9,925,150 ("the '150 patent") are listed in the electronic version of the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for Neupro®.

ANSWER: Admitted.

15. MTI filed ANDA No. 209982 seeking approval from the FDA for its rotigotine transdermal formulations (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours).

ANSWER: On information and belief, Plaintiffs admit that MTI submitted an ANDA to FDA seeking approval to engage in the commercial manufacture, use, or sale of generic versions of Plaintiffs' Neupro® transdermal system prior to the expiration of the '979, '980, '589, '174, '591, and '150 patents and that the ANDA was assigned No. 209982 by FDA. To the extent Paragraph 15 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

16. By letter dated February 27, 2017, MTI notified Counterclaim Defendants in writing that it had filed ANDA No. 209982 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '979 and '980 patents, among others, are invalid, unenforceable, and/or will not be infringed by the products that are the subject of ANDA No. 209982.

ANSWER: Plaintiffs admit that representatives of UCB and LTS received a letter purportedly sent on behalf of MTI, dated February 27, 2017, stating that MTI had submitted a purported Paragraph IV certification for patents, including the '979 and '980 patents, in connection with ANDA No. 209982. MTI's letter speaks for itself. To the extent Paragraph 16 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

17. By letter dated July 29, 2019, MTI notified Counterclaim Defendants in writing that it had filed ANDA No. 209982 with a Paragraph IV Certification that the '589 and '174 patents are invalid, unenforceable, and/or will not be infringed by the products that are the subject of ANDA No. 209982.

ANSWER: Plaintiffs admit that representatives of UCB and LTS received a letter purportedly sent on behalf of MTI, dated July 29, 2019, stating that MTI had submitted a purported Paragraph IV certification for the '589 and '174 patents. MTI's letter speaks for itself. To the extent Paragraph 17 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

18. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), MTI's Notice Letters were accompanied by a detailed statement of the factual and legal bases for MTI's Paragraph IV

Certifications that the '979, '980, '589 and '174 patents are invalid, unenforceable, and/or will not be infringed.

ANSWER: Plaintiffs admit that MTI's letters dated February 27, 2017 and July 29, 2019 represented that MTI had submitted a purported Paragraph IV certification for the '979, '980, '589, and '174 patents stating various arguments as set forth in the letters, which speak for themselves. To the extent Paragraph 18 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

19. On March 24, 2017, Counterclaim Defendants and UCB Manufacturing filed suit against MTI, Mylan Pharmaceuticals, Inc. and Mylan, Inc., in the United States District Court for the District of Delaware in *UCB, Inc. , et al. v. Mylan Techs., Inc., et al.*, No. 17-cv-322-LPS (D. Del.) ("Delaware -322 Action"), alleging infringement of the '979 and '980 patents, as well as the '591 patent and U.S. Patent Nos. 6,884,434 and 7,413,747. No. 171-cv-322-LPS [sic], ECF No. 1 (D. Del. Mar. 24, 2017).

ANSWER: Plaintiffs admit that on March 24, 2017, Plaintiffs and UCB Manufacturing Ireland Limited brought an action for patent infringement against MTI, Mylan Pharmaceuticals, Inc., and Mylan, Inc. in the United States District Court for the District of Delaware in the Delaware -322 Action alleging, *inter alia*, infringement of claims of the '979 and '980 patents based on the versions of MTI's proposed rotigotine transdermal system in ANDA No. 209982 then proposed for approval at that time. To the extent Paragraph 19 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

20. On May 30, 2018, Counterclaim Defendants and UCB Manufacturing served Initial Infringement Contentions in the Delaware -322 Action that did not include any allegations of infringement with respect to the '979 or '980 patents. No. 171-cv-322-LPS [sic], ECF No. 66 (D. Del. Mar. 24, 2017, Notice of Service).

ANSWER: Plaintiffs admit that Plaintiffs and UCB Manufacturing Ireland Limited's Initial Infringement Contentions in the Delaware -322 Action were served on May 30, 2018, and did not include contentions that MTI's rotigotine transdermal system in ANDA No. 209982 then proposed for approval at that time infringed claims of the '979 or '980 patents. To the extent

Paragraph 20 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

21. On August 26, 2019, the Delaware -322 Action was transferred to this district and was assigned civil action number 19-cv-148-WKS (D. Vt.) (“Vermont -148 Action”). No. 17-cv-322-LPS, ECF No. 92 (D. Del. Aug. 26, 2019).

ANSWER: Admitted.

22. Thereafter, counsel for Counterclaim Defendants and UCB Manufacturing and counsel for MTI began negotiating terms for a covenant not to sue that would cover patents not asserted against MTI, including the ’979 and ’980 patents. Notwithstanding those negotiations, on June 16, 2020, Counterclaim Defendants and UCB Manufacturing unilaterally executed and served on MTI a covenant not to sue with respect to the ’979 and ’980 patents, among others (“June 16, 2020 Covenant”). Counterclaim Defendants and UCB Manufacturing covenanted not to sue MTI “for any and all claims that the manufacture, use, sale, offer for sale, distribution, and/or importation of the drug products described in the Mylan ANDA . . . infringes any claim of the ’979, ’980, ’591, or ’150 patents.” June 16, 2020 Covenant at ¶ 2. Pursuant to the terms of the June 16, 2020 Covenant, if MTI “modifies, adds, removes, or alters components in the Mylan ANDA Products, or steps that are used in their manufacture, so as to alter the infringement analysis with respect to any claim of the ’979, ’980, ’591, or ’150 Patents – th[e] Covenant will not constitute a promise by Plaintiffs not to sue Mylan based on any such revised (or Supplemental) ANDA, or any accordingly modified product or its manufacture.” *Id.* at ¶ 3.

ANSWER: Plaintiffs admit that at least from 2018 through 2020, counsel for Plaintiffs and UCB Manufacturing Ireland Limited and counsel for MTI communicated with each other, with MTI’s counsel referencing potentially streamlining litigation proceedings. Plaintiffs admit that, on or around June 16, 2020, Plaintiffs and UCB Manufacturing Ireland Limited covenanted not to sue MTI “for any and all claims that the manufacture, use, sale, offer for sale, distribution, and/or importation of the drug products described in the Mylan ANDA . . . infringes any claim of the ’979, ’980, ’591, or ’150 patents,” with the June 16, 2020 Covenant specifically stating, *inter alia*, that “[t]he Covenant set forth herein shall apply to the formulation of the Mylan ANDA Products as described in the Mylan ANDA provided to Plaintiffs as of May 27, 2020,” and that if MTI “modifies, adds, removes, or alters components in the Mylan ANDA Products, or steps that are used in their manufacture, so as to alter the infringement analysis with respect to any claim of

the '979, '980, '591, or '150 Patents – th[e] Covenant will not constitute a promise by Plaintiffs not to sue Mylan based on any such revised (or Supplemental) ANDA, or any accordingly modified product or its manufacture,” as more specifically set forth in the full June 16, 2020 Covenant, which speaks for itself. To the extent Paragraph 22 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

23. On July 17, 2020, the parties in the Vermont -148 Action stipulated, and the Court subsequently so ordered, that the claims against MTI with respect to the '979 and '980 patents, among others, were “dismissed with prejudice in accordance with a Covenant Not to Sue dated June 16, 2020 . . .” No. 19-cv-148-WKS, ECF No. 97 at ¶ 1 (D. Vt. July 20, 2020).

ANSWER: Plaintiffs admit that on July 17, 2020, the parties in the Vermont -148 Action filed a Stipulation and Order for Dismissal (Dkt. 96) that was entered by the Court on July 20, 2020 (Dkt. 97), which, *inter alia*, states that:

Plaintiffs’ claims against Mylan as pled in the above-captioned action with respect to U.S. Patent Nos. 7,413,747 (“the '747 Patent”); 8,246,979 (“the '979 Patent”); 8,246,980 (“the '980 Patent”); and 8,617,591 (“the '591 Patent”) (collectively the “Covenant Patents”) are hereby dismissed with prejudice in accordance with a Covenant Not to Sue dated June 16, 2020 (the “Covenant”). This dismissal is made without prejudice to Plaintiffs’ ability to assert the Covenant Patents for any other ANDA or as provided in the Covenant.

Id. at ¶ 1. The June 16, 2020 Covenant speaks for itself. To the extent Paragraph 23 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

24. Separately, on July 16, 2019, Counterclaim Defendants filed suit against MTI in this district in *UCB, Inc., et al. v. Mylan Techs., Inc.*, No. 19-cv-128-CR (D. Vt.) (“Vermont -128 Action”) alleging infringement of the '589 and '174 patents. No. 19-cv-128-CR, ECF No. 1 (D. Vt. July 16, 2019).

ANSWER: Plaintiffs admit that on July 16, 2019, Plaintiffs brought an action for patent infringement against MTI in this district in the Vermont -128 Action alleging, *inter alia*, infringement of claims of the '589 and '174 patents based on the versions of MTI’s proposed rotigotine transdermal system in ANDA No. 209982 then proposed for approval at that time. To

the extent Paragraph 24 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

25. Following service of MTI's July 29, 2019 Notice Letter directed to the '589 and '174 patents, Counterclaim Defendants filed an Amended Complaint in the Vermont -128 Action. No. 19-cv-128-CR, ECF No. 16 (D. Vt. Aug. 12, 2019).

ANSWER: Plaintiffs admit that they filed an Amended Complaint in the Vermont -128 Action on August 12, 2019, which is after the date on the face of MTI's July 29, 2019 letter. To the extent Paragraph 25 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

26. On May 13, 2020, the parties in the Vermont -128 Action stipulated, and this Court so ordered, that: (1) "Plaintiffs narrow the set of asserted claims to Claims 1-3, 4, 7, and 10-12 of the '589 patent and Claims 1, 2, 5-6 and 14-15 of the '174 patent." And, (2) "For purposes of this proceeding only, Mylan will not contest allegations of infringement for Claims 1-3, 4, 7, and 10-12 of the '589 patent and Claims 1-2, 5-6 and 14-15 of the '174 patent." No. 19-cv-128-CR, ECF No. 98 (D. Vt. May 13, 2020).

ANSWER: Plaintiffs admit that on May 13, 2020, Counterclaim Defendants entered into a stipulation with MTI in the Vermont -128 Action, and this Court so ordered. The stipulation and order speak for themselves. To the extent Paragraph 26 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

27. On March 26, 2021, the United States District Court for the District of Delaware issued Post-Trial Findings of Fact and Conclusions of Law in *UCB, Inc. et al. v. Actavis Laboratories UT, Inc.*, No. 19-cv-474 at ECF No. 191 (D. Del. Mar. 26, 2021), holding that claims 1-3, 7, and 10-12 of the '589 patent were invalid (the "Actavis Action"). Final Judgment was entered in the Actavis Action on April 7, 2021. *Id.* at ECF No. 196 (D. Del. Apr. 7, 2021).

ANSWER: Plaintiffs admit that the United States District Court for the District of Delaware issued Post-Trial Findings of Fact and Conclusions of Law in the Actavis Action as set forth in that opinion, and that Final Judgement was entered in that case on April 7, 2021, as set forth in that judgment. The court's order and judgment speak for themselves. To the extent

Paragraph 27 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

28. On May 3, 2021, Plaintiffs filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit from the decision in the Actavis Action, *see* No. 19-cv-474, ECF No. 200 (D. Del. May 3, 2021), with the Actavis appeal subsequently being docketed at No. 21-1924 (Fed. Cir. May 6, 2021).

ANSWER: Admitted.

29. On June 8, 2021, the parties in the Vermont -128 Action filed a Proposed Judgment and Stipulated Dismissal. No. 19-cv-128-CR, ECF No. 137 (D. Vt. June 8, 2021). The parties' submission requested, among other things, that the trial record, Final Judgment, and Findings of Fact and Conclusions of Law from the Actavis Action concerning the '589 Patent be adopted, "preserving the parties' right to appeal such decision as if issued by this Court." *Id* at 2. Judgment was proposed to be "entered in favor of Mylan and against Plaintiffs with respect to the validity of the claims of the '589 Patent, and all claims for relief requested in Plaintiffs' Amended Complaint for Patent Infringement with respect to the '589 Patent (Doc. 16) are denied . . . , and that Judgment be "entered in favor of Mylan and against Plaintiffs on Count 2 of Mylan's Counterclaims (Doc. 21) that the Asserted Claims of the '589 Patent are invalid . . ." *Id*. As to the '174 Patent claims, the parties proposed that "[a]ll claims, defenses, and requests for relief pled by Plaintiffs and Mylan with respect to the '174 Patent are dismissed, with prejudice . . ." *Id*. This Court so ordered the Proposed Judgment and Stipulated Dismissal. No. 19-cv-128-CR, ECF No. 138 (D. Vt. June 8, 2021).

ANSWER: Plaintiffs admit that the parties filed a Proposed Judgment and Stipulated Dismissal on June 8, 2021, as set forth in that document. The Proposed Judgement and Stipulated Dismissal and this Court's order speak for themselves. To the extent Paragraph 29 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

30. By letter dated October 27, 2022, MTI notified Counterclaim Defendants in writing that it had filed ANDA No. 209982 with a Paragraph IV Certification that the '979, '980, '589, '174, '150 and '591 patents are invalid, unenforceable, and/or will not be infringed by the products that are the subject of ANDA No. 209982.

ANSWER: Plaintiffs admit that representatives of UCB and LTS received a letter purportedly sent on behalf of MTI, dated October 27, 2022, stating that MTI had submitted a purported Paragraph IV certification for patents including the '979, '980, '589, '174, '150, and '591 patents in connection with ANDA No. 209982, as more specifically set forth in the letter.

MTI's letter speaks for itself. To the extent Paragraph 30 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

31. The Paragraph IV Certification referenced in MTI's October 27, 2022 Notice Letter was submitted as part of an amendment to ANDA No. 209982 which included changes to certain components of MTI's ANDA Products disclosed therein. The changes made in the amendment to MTI's ANDA are insubstantial. The products that are the subject thereof are essentially the same as the products described in the ANDA prior to the amendment, such that they do not alter the infringement analysis with respect to any of the patents presently asserted by Counterclaim Defendants.

ANSWER: Plaintiffs admit that the letter purportedly sent on behalf of MTI dated October 27, 2022 represented that MTI was providing the letter to Plaintiffs "based on an ANDA amendment submitted to FDA addressing previous FDA inquiries sent to [MTI]," as more specifically set forth in the letter. Among other things, the letter represented that MTI's ANDA amendment "includes changes to the components of [MTI's] ANDA Products." On information and belief, the changes made in MTI's ANDA amendment to at least the components of the MTI ANDA Product are substantial. On information and belief, MTI has revised and/or supplemented the ANDA and modified its proposed production and the manufacture thereof. The MTI ANDA Product now proposed in MTI's ANDA following the amendment is not essentially the same as the MTI ANDA Product proposed before the amendment. To the extent Paragraph 31 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

32. The changes made in the amendment to MTI's ANDA were made in view of the covenant not to sue related to the '979 and '980 patents, as well as the dismissals with prejudice and judgments entered with respect to the '979, '980, '589 and '174 patents, all of which were agreed to between MTI and Counterclaim Defendants.

ANSWER: Plaintiffs note that, on its face, the allegations in this paragraph conflict with the allegations set forth in Paragraph 22. Plaintiffs note that the covenant not to sue referenced in Paragraph 22 and the prior dismissals with prejudice and judgments discussed *supra* speak for themselves. Plaintiffs lack knowledge or information sufficient to form a belief about the truth of

the allegation as to the changes made in the amendment to MTI's ANDA being made "in view" of the documents referenced in the allegation and, accordingly, deny the foregoing allegation. To the extent Paragraph 32 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

COUNT I: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '979 PATENT

33. MTI repeats and realleges the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 32 above, as if fully set forth herein.

34. Plaintiffs have accused MTI of infringing claims of the '979 patent in connection with ANDA No. 209982.

ANSWER: Plaintiffs admit that they have accused MTI of infringing claims of the '979 patent in connection with MTI's ANDA No. 209982 and amendments thereto as more fully set forth in Plaintiffs' Complaint. To the extent Paragraph 34 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

35. MTI denies infringement of any valid, enforceable, properly construed claim of the '979 patent, including for the reasons set forth in the detailed statement included with MTI's Notice Letters directed to the '979 patent.

ANSWER: Paragraph 35 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that in this counterclaim MTI purports to deny infringement of any valid, enforceable, properly construed claim of the '979 patent for reasons set forth in MTI's letters to Plaintiffs, while Plaintiffs have alleged infringement as set forth in the Complaint. To the extent Paragraph 35 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

36. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of MTI's ANDA Product will not constitute infringement of any valid, enforceable, properly construed claim of the '979 patent.

ANSWER: Denied.

37. MTI is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of MTI's ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '979 patent.

ANSWER: Denied.

38. Unless Counterclaim Defendants are enjoined, MTI believes that Counterclaim Defendants will continue to assert that MTI's ANDA Product is infringing the claims of the '979 patent, and will continue to interfere with MTI's business with respect to MTI's ANDA Product and its manufacture, use, offer for sale and sale.

ANSWER: Plaintiffs admit that they have asserted that MTI has infringed, and will continue to infringe, claims of the '979 patent with respect to the MTI ANDA and amendments and the MTI ANDA Products as more fully set forth in Plaintiffs' Complaint. Plaintiffs lack knowledge or information sufficient to form a belief about MTI's belief as set forth in Paragraph 38, and accordingly, Plaintiffs deny these allegations. To the extent Paragraph 38 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

39. MTI will be irreparably harmed if Counterclaim Defendants are not enjoined from continuing to assert the '979 patent and from interfering with MTI's business.

ANSWER: Denied.

40. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '979 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

ANSWER: Paragraph 40 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that they have asserted that MTI has infringed, and will continue to infringe, claims of the '979 patent with respect to the MTI ANDA and amendments and the MTI ANDA Products as more fully set forth in Plaintiffs' Complaint.

COUNT II: DECLARATORY JUDGMENT OF INVALIDITY OF THE '979 PATENT

41. MTI repeats and realleges the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 40 above, as if fully set forth herein.

42. The claims of the '979 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially created bases for invalidation, and including for at least the reasons set forth in the detailed statement included with MTI's Notice Letters directed to the '979 patent.

ANSWER: Denied.

43. The alleged invention of the '979 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the '979 patent in the United States.

ANSWER: Denied.

44. The alleged invention of the '979 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '979 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '979 patent and would have had a reasonable expectation of success in doing so.

ANSWER: Denied.

45. The claims of the '979 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '979 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

ANSWER: Denied.

46. The claims of the '979 patent do not inform those skilled in the art about the scope of the invention with reasonable certainty, and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

ANSWER: Denied.

47. MTI is entitled to a judicial declaration that the claims of the '979 patent are invalid.

ANSWER: Denied.

COUNT III: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '980 PATENT

48. MTI repeats and realleges the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 47 above, as if fully set forth herein.

49. Plaintiffs have accused MTI of infringing claims of the '980 patent in connection with ANDA No. 209982.

ANSWER: Plaintiffs admit that they have accused MTI of infringing claims of the '980 patent in connection with MTI's ANDA No. 209982 and amendments thereto as more fully set forth in Plaintiffs' Complaint. To the extent Paragraph 49 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

50. MTI denies infringement of any valid, enforceable, properly construed claim of the '980 patent, including for the reasons set forth in the detailed statement included with MTI's Notice Letters directed to the '980 patent.

ANSWER: Paragraph 50 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that in this counterclaim MTI purports to deny infringement of any valid, enforceable, properly construed claim of the '980 patent for reasons set forth in MTI's letters to Plaintiffs, while Plaintiffs have alleged infringement as set forth in the Complaint. To the extent Paragraph 50 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

51. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of MTI's ANDA Product will not constitute infringement of any valid, enforceable, properly construed claim of the '980 patent.

ANSWER: Denied.

52. MTI is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of MTI's ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '980 patent.

ANSWER: Denied.

53. Unless Counterclaim Defendants are enjoined, MTI believes that Counterclaim Defendants will continue to assert that MTI's ANDA Product is infringing the claims of the '980 patent, and will continue to interfere with MTI's business with respect to MTI's ANDA Product and its manufacture, use, offer for sale and sale.

ANSWER: Plaintiffs admit that they have asserted that MTI has infringed, and will continue to infringe, claims of the '980 patent with respect to the MTI ANDA and amendments and the MTI ANDA Products as more fully set forth in Plaintiffs' Complaint. Plaintiffs lack knowledge or information sufficient to form a belief about MTI's belief as set forth in Paragraph 53, and accordingly, Plaintiffs deny these allegations. To the extent Paragraph 53 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

54. MTI will be irreparably harmed if Counterclaim Defendants are not enjoined from continuing to assert the '980 patent and from interfering with MTI's business.

ANSWER: Denied.

55. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '980 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

ANSWER: Paragraph 55 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that they have asserted that MTI has infringed, and will continue to infringe, claims of the '980 patent with respect to the MTI ANDA and amendments and the MTI ANDA Products as more fully set forth in Plaintiffs' Complaint.

COUNT IV: DECLARATORY JUDGMENT OF INVALIDITY OF THE '980 PATENT

56. MTI repeats and realleges the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 55 above, as if fully set forth herein.

57. The claims of the '980 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially created bases for invalidation, and including for at least the reasons set forth in the detailed statement included with MTI's Notice Letters directed to the '980 patent.

ANSWER: Denied.

58. The alleged invention of the '980 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the '980 patent in the United States.

ANSWER: Denied.

59. The alleged invention of the '980 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '980 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '980 patent and would have had a reasonable expectation of success in doing so.

ANSWER: Denied.

60. The claims of the '980 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '980 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

ANSWER: Denied.

61. The claims of the '980 patent do not inform those skilled in the art about the scope of the invention with reasonable certainty, and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

ANSWER: Denied.

62. MTI is entitled to a judicial declaration that the claims of the '980 patent are invalid.

ANSWER: Denied.

COUNT V: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '589 PATENT

63. MTI repeats and realleges the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 62 above, as if fully set forth herein.

64. Plaintiffs have accused MTI of infringing claims of the '589 patent in connection with ANDA No. 209982.

ANSWER: Plaintiffs admit that they have accused MTI of infringing claims of the '589 patent in connection with MTI's ANDA No. 209982 and amendments thereto as more fully set forth in Plaintiffs' Complaint. To the extent Paragraph 64 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

65. MTI denies infringement of any valid, enforceable, properly construed claim of the '589 patent, including for the reasons set forth in the detailed statement included with MTI's Notice Letters directed to the '589 patent.

ANSWER: Paragraph 65 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that in this counterclaim MTI purports to deny infringement of any valid, enforceable, properly construed claim of the '589 patent for reasons set forth in MTI's letters to Plaintiffs, while Plaintiffs have alleged infringement as set forth in the Complaint. To the extent Paragraph 65 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

66. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of MTI's ANDA Product will not constitute infringement of any valid, enforceable, properly construed claim of the '589 patent.

ANSWER: Denied.

67. MTI is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of MTI's ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '589 patent.

ANSWER: Denied.

68. Unless Counterclaim Defendants are enjoined, MTI believes that Counterclaim Defendants will continue to assert that MTI's ANDA Product is infringing the claims of the '589 patent, and will continue to interfere with MTI's business with respect to MTI's ANDA Product and its manufacture, use, offer for sale and sale.

ANSWER: Plaintiffs admit that they have asserted that MTI has infringed, and will continue to infringe, claims of the '589 patent with respect to the MTI ANDA and amendments and the MTI ANDA Products as more fully set forth in Plaintiffs' Complaint. Plaintiffs lack knowledge or information sufficient to form a belief about MTI's belief as set forth in Paragraph 68, and accordingly, Plaintiffs deny these allegations. To the extent Paragraph 68 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

69. MTI will be irreparably harmed if Counterclaim Defendants are not enjoined from continuing to assert the '589 patent and from interfering with MTI's business.

ANSWER: Denied.

70. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '589 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

ANSWER: Paragraph 70 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that they have asserted that MTI has infringed, and will continue to infringe, claims of the '589 patent with respect to the MTI ANDA and amendments and the MTI ANDA Products as more fully set forth in Plaintiffs' Complaint.

COUNT VI: DECLARATORY JUDGMENT OF INVALIDITY OF THE '589 PATENT

71. MTI repeats and realleges the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 70 above, as if fully set forth herein.

72. The claims of the '589 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not

limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially created bases for invalidation, and including for at least the reasons set forth in the detailed statement included with MTI's Notice Letters directed to the '589 patent.

ANSWER: Denied.

73. The alleged invention of the '589 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the '589 patent in the United States.

ANSWER: Denied.

74. The alleged invention of the '589 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '589 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '589 patent and would have had a reasonable expectation of success in doing so.

ANSWER: Denied.

75. The claims of the '589 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '589 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

ANSWER: Denied.

76. The claims of the '589 patent do not inform those skilled in the art about the scope of the invention with reasonable certainty, and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

ANSWER: Denied.

77. MTI is entitled to a judicial declaration that the claims of the '589 patent are invalid.

ANSWER: Denied.

COUNT VII: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '174 PATENT

78. MTI repeats and realleges the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 77 above, as if fully set forth herein.

79. Plaintiffs have accused MTI of infringing claims of the '174 patent in connection with ANDA No. 209982.

ANSWER: Plaintiffs admit that they have accused MTI of infringing claims of the '174 patent in connection with MTI's ANDA No. 209982 and amendments thereto as more fully set forth in Plaintiffs' Complaint. To the extent Paragraph 79 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

80. MTI denies infringement of any valid, enforceable, properly construed claim of the '174 patent, including for the reasons set forth in the detailed statement included with MTI's Notice Letters directed to the '174 patent.

ANSWER: Paragraph 80 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that in this counterclaim MTI purports to deny infringement of any valid, enforceable, properly construed claim of the '174 patent for reasons set forth in MTI's letters to Plaintiffs, while Plaintiffs have alleged infringement as set forth in the Complaint. To the extent Paragraph 80 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

81. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of MTI's ANDA Product will not constitute infringement of any valid, enforceable, properly construed claim of the '174 patent.

ANSWER: Denied.

82. MTI is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of MTI's ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '174 patent.

ANSWER: Denied.

83. Unless Counterclaim Defendants are enjoined, MTI believes that Counterclaim Defendants will continue to assert that MTI's ANDA Product is infringing the claims of the '174

patent, and will continue to interfere with MTI's business with respect to MTI's ANDA Product and its manufacture, use, offer for sale and sale.

ANSWER: Plaintiffs admit that they have asserted that MTI has infringed, and will continue to infringe, claims of the '174 patent with respect to the MTI ANDA and amendments and the MTI ANDA Products as more fully set forth in Plaintiffs' Complaint. Plaintiffs lack knowledge or information sufficient to form a belief about MTI's belief as set forth in Paragraph 83, and accordingly, Plaintiffs deny these allegations. To the extent Paragraph 83 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

84. MTI will be irreparably harmed if Counterclaim Defendants are not enjoined from continuing to assert the '174 patent and from interfering with MTI's business.

ANSWER: Denied.

85. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '174 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

ANSWER: Paragraph 85 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that they have asserted that MTI has infringed, and will continue to infringe, claims of the '174 patent with respect to the MTI ANDA and amendments and the MTI ANDA Products as more fully set forth in Plaintiffs' Complaint.

COUNT VIII: DECLARATORY JUDGMENT OF INVALIDITY OF THE '174 PATENT

86. MTI repeats and realleges the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 85 above, as if fully set forth herein.

87. The claims of the '174 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially created bases for invalidation, and including for at least the reasons set forth in the detailed statement included with MTI's Notice Letter directed to the '174 patent.

ANSWER: Denied.

88. The alleged invention of the '174 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the '174 patent in the United States.

ANSWER: Denied.

89. The alleged invention of the '174 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '174 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '174 patent and would have had a reasonable expectation of success in doing so.

ANSWER: Denied.

90. The claims of the '174 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '174 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

ANSWER: Denied.

91. The claims of the '174 patent do not inform those skilled in the art about the scope of the invention with reasonable certainty, and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

ANSWER: Denied.

92. MTI is entitled to a judicial declaration that the claims of the '174 patent are invalid.

ANSWER: Denied.

**COUNT IX: DECLARATORY JUDGMENT OF UNENFORCEABILITY DUE TO
UNCLEAN HANDS AND/OR PATENT MISUSE**

93. MTI repeats and realleges the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 92 above, as if fully set forth herein.

94. Counterclaim Defendants have accused MTI of infringing claims of the '979, '980, '589, and '174 patent in connection with the MTI ANDA Product, despite having knowledge of the covenant not to sue with respect to the '979 and '980 patent, having knowledge of the dismissals with prejudice related to the '979, '980 and '174 patents, and having knowledge that "judgment [was] entered in favor of [MTI] and against [Counterclaim Defendants] with respect to the validity of the claims of the '589 Patent"

ANSWER: Plaintiffs admit that they have accused MTI of infringing claims of the '979, '980, '589, and '174 patents in connection with the MTI ANDA and amendments and the MTI ANDA Product as more fully set forth in Plaintiffs' Complaint. Plaintiffs further admit that their Complaint includes specific allegations regarding the June 16, 2020 Covenant, as well as the orders and judgments in, *inter alia*, the Vermont -128 Action, the Delaware -322 Action, and the Vermont -148 Action, as more specifically set forth in the Complaint. To the extent Paragraph 94 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

95. Counterclaim Defendants' allegations of infringement are therefore grounded in fraud, deceit and/or bad faith, with the intended purpose of harming MTI by denying its rights to enjoy the releases provided by way of a covenant and to operate as necessary in view of the dismissals with prejudice and judgments entered with respect to each of the '979, '980, '589, and '174 patents.

ANSWER: Denied.

96. By maintaining these allegations of infringement, Counterclaim Defendants are improperly seeking to broaden the scope of their rights to exclude under the asserted patents and are seeking to block competition in the market for rotigotine transdermal formulations (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours).

ANSWER: Denied.

97. MTI is entitled to a judicial declaration that the '979, '980, '589, and '174 patents are unenforceable under the doctrines of unclean hands and/or patent misuse.

ANSWER: Denied.

COUNT X: DECLARATORY JUDGMENT OF ISSUE AND/OR CLAIM PRECLUSION

98. MTI repeats and realleges the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 97 above, as if fully set forth herein.

99. Each of the aforementioned Actions between MTI and Counterclaim Defendants involved the same parties, the same ANDA No. 209982, and at least the '979, '980, '589 and '174 patents.

ANSWER: Denied.

100. With respect to each of the '979, '980, '589 and '174 patents, Counterclaim Defendants could have, but did not, allege infringement of certain patent claims.

ANSWER: Paragraph 100 contains legal conclusions and allegations to which no answer is required. To the extent a response is required, Plaintiffs deny any remaining allegations.

101. Counterclaim Defendants have now accused MTI of infringing claims of the '979, '980, '589, and '174 patent in connection with the MTI ANDA Product, despite having knowledge of the covenant not to sue with respect to the '979 and '980 patent, having knowledge of the dismissals with prejudice related to the '979, '980 and '174 patents, and having knowledge that "judgment [was] entered in favor of [MTI] and against [Counterclaim Defendants] with respect to the validity of the claims of the '589 Patent"

ANSWER: Plaintiffs admit that they have accused MTI of infringing claims of the '979, '980, '589, and '174 patents in connection with the MTI ANDA and amendments and MTI ANDA Product as more fully set forth in Plaintiffs' Complaint. Plaintiffs further admit that their Complaint includes specific allegations regarding the June 16, 2020 Covenant, as well as the orders and judgments in, *inter alia*, the Vermont -128 Action, the Delaware -322 Action, and the Vermont -148 Action, as more specifically set forth in the Complaint. To the extent Paragraph 101 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

102. The changes made in the amendment to MTI's ANDA No. 209982 are insubstantial and the products described before the amendment are essentially the same as those described after, such that they do not alter the infringement analysis with respect to any of the '979, '980, '589 or '174 patents.

ANSWER: As more specifically set forth in Plaintiffs' Complaint, the letter purportedly sent on behalf of MTI dated October 27, 2022 represented that MTI was providing the letter to

Plaintiffs “based on an ANDA amendment submitted to FDA addressing previous FDA inquiries sent to [MTI].” Specifically, the letter represented that MTI’s ANDA amendment “includes changes to the components of [MTI’s] ANDA Products.” Applicable regulations require that “[a]n amendment to an ANDA is required to contain an appropriate patent certification . . . if approval is sought . . . [t]o make other than minor changes in a product formulation . . .” 21 C.F.R. § 314.96(d)(1)(iii). On information and belief, the changes made in MTI’s ANDA amendment to at least the components of the MTI ANDA Product are substantial. On information and belief, MTI has revised and/or supplemented the ANDA and modified its proposed production and the manufacture thereof. The MTI ANDA Product now proposed in MTI’s ANDA following the amendment is not essentially the same as the MTI ANDA Product proposed before the amendment. To the extent Paragraph 102 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

103. MTI will be materially prejudiced if Counterclaim Defendants are permitted to maintain allegations of infringement of the ’979, ’980, ’589 and ’174 patents. As a result, Counterclaim Defendants’ claims of infringement under the ’979, ’980, ’589 and ’174 patents against MTI should be barred based on issue and/or claim preclusion.

ANSWER: Denied.

COUNT XI: BREACH OF COVENANT NOT TO SUE

104. MTI repeats and realleges the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 103 above, as if fully set forth herein.

105. Counterclaim Defendants covenanted not to sue MTI “for any and all claims that the manufacture, use, sale, offer for sale, distribution, and/or importation of the drug products described in the Mylan ANDA . . . infringes any claim of the ’979, ’980, ’591, or ’150 patents.”

ANSWER: Plaintiffs admit that, on or around June 16, 2020, Plaintiffs and UCB Manufacturing Ireland Limited covenanted not to sue MTI “for any and all claims that the

manufacture, use, sale, offer for sale, distribution, and/or importation of the drug products described in the Mylan ANDA . . . infringes any claim of the '979, '980, '591, or '150 patents," with the June 16, 2020 Covenant specifically stating, *inter alia*, that "[t]he Covenant set forth herein shall apply to the formulation of the Mylan ANDA Products as described in the Mylan ANDA provided to Plaintiffs as of May 27, 2020," and that if MTI "modifies, adds, removes, or alters components in the Mylan ANDA Products, or steps that are used in their manufacture, so as to alter the infringement analysis with respect to any claim of the '979, '980, '591, or '150 Patents – th[e] Covenant will not constitute a promise by Plaintiffs not to sue Mylan based on any such revised (or Supplemental) ANDA, or any accordingly modified product or its manufacture," as more specifically set forth in the full June 16, 2020 Covenant, which speaks for itself. To the extent Paragraph 105 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

106. The covenant remains binding to cover amendments to MTI's ANDA unless the amendment seeks to "change any indication(s) sought therein," or includes changes to the components or manufacturing steps that "alter the infringement analysis with respect to any claim of the '979, '980, '591, or '150 patents . . ."

ANSWER: Paragraph 106 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that the June 16, 2020 Covenant contains the crop-quoted language quoted in Paragraph 106, as well as other language set forth in the full June 16, 2020 Covenant, which speaks for itself. To the extent Paragraph 106 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

107. The changes made in the amendment to MTI's ANDA do not seek to change any indications sought therein and do not alter the infringement analysis with respect to any claim of the asserted '979 or '980 patents.

ANSWER: As more specifically set forth in Plaintiffs' Complaint, the letter purportedly sent on behalf of MTI dated October 27, 2022 represented that MTI was providing the letter to

Plaintiffs “based on an ANDA amendment submitted to FDA addressing previous FDA inquiries sent to [MTI].” Specifically, the letter represented that MTI’s ANDA amendment “includes changes to the components of [MTI’s] ANDA Products.” Applicable regulations require that “[a]n amendment to an ANDA is required to contain an appropriate patent certification . . . if approval is sought . . . [t]o make other than minor changes in a product formulation” 21 C.F.R. § 314.96(d)(1)(iii). While the allegation above does not identify the specific amendment to which it relates, nor prior related portions of the ANDA, the ANDA and amendments thereto speak for themselves at least with respect to any indications for use purportedly sought by MTI. However, on information and belief, the changes made in MTI’s ANDA amendment to at least the components of the MTI ANDA Product are substantial. On information and belief, MTI has revised and/or supplemented the ANDA and modified its proposed production and the manufacture thereof. The MTI ANDA Product now proposed in MTI’s ANDA following the amendment is not essentially the same as the MTI ANDA Product proposed before the amendment. To the extent Paragraph 102 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

108. Counterclaim Defendants have now accused MTI of infringing claims of the ’979 and ’980 patents in connection with the MTI ANDA Product by filing suit on the same, and have therefore breached the covenant not to sue.

ANSWER: Plaintiffs admit that they have accused MTI of infringing claims of the ’979 and ’980 patents with respect to the MTI ANDA Product now proposed following the amendment to MTI’s ANDA as more fully set forth in Plaintiffs’ Complaint. Plaintiffs deny that they have breached the June 16, 2020 Covenant. To the extent Paragraph 108 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

109. MTI will be materially prejudiced if Counterclaim Defendants are permitted to maintain allegations of infringement of the '979 and '980 patents in direct violation of the covenant not to sue.

ANSWER: Denied.

110. Counterclaim Defendants should be enjoined from maintaining claims of infringement under the '979 and '980 patents against MTI.

ANSWER: Denied.

COUNT XII: EQUITABLE ESTOPPEL

111. MTI repeats and realleges the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 110 above, as if fully set forth herein.

112. Counterclaim Defendants covenanted not to sue MTI “for any and all claims that the manufacture, use, sale, offer for sale, distribution, and/or importation of the drug products described in the Mylan ANDA . . . infringes any claim of the '979, '980, '591, or '150 patents.”

ANSWER: Plaintiffs admit that, on or around June 16, 2020, Plaintiffs and UCB Manufacturing Ireland Limited covenanted not to sue MTI “for any and all claims that the manufacture, use, sale, offer for sale, distribution, and/or importation of the drug products described in the Mylan ANDA . . . infringes any claim of the '979, '980, '591, or '150 patents,” with the June 16, 2020 Covenant specifically stating, *inter alia*, that “[t]he Covenant set forth herein shall apply to the formulation of the Mylan ANDA Products as described in the Mylan ANDA provided to Plaintiffs as of May 27, 2020,” and that if MTI “modifies, adds, removes, or alters components in the Mylan ANDA Products, or steps that are used in their manufacture, so as to alter the infringement analysis with respect to any claim of the '979, '980, '591, or '150 Patents – th[e] Covenant will not constitute a promise by Plaintiffs not to sue Mylan based on any such revised (or Supplemental) ANDA, or any accordingly modified product or its manufacture,” as more specifically set forth in the full June 16, 2020 Covenant, which speaks for itself. To the extent

Paragraph 112 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

113. The covenant remains binding to cover amendments to MTI's ANDA unless the amendment seeks to "change any indication(s) sought therein," or includes changes to the components or manufacturing steps that "alter the infringement analysis with respect to any claim of the '979, '980, '591, or '150 patents"

ANSWER: Paragraph 113 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that the June 16, 2020 Covenant contains the crop-quoted language quoted in Paragraph 113, as well as other language set forth in the full June 16, 2020 Covenant, which speaks for itself. To the extent Paragraph 113 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

114. The changes made in the amendment to MTI's ANDA were made in view of the covenant not to sue related to the '979 and '980 patents, as well as the dismissals with prejudice and judgments entered with respect to the '979, '980, '589 and '174 patents, all of which were agreed to between MTI and Counterclaim Defendants.

ANSWER: Plaintiffs note that, on its face, the allegations in this paragraph conflict with the allegations set forth in Paragraph 22. Plaintiffs note that the covenant not to sue referenced in Paragraph 22 and the prior dismissals with prejudice and judgments discussed *supra* speak for themselves. Plaintiffs lack knowledge or information sufficient to form a belief about the truth of the allegation as to the changes made in the amendment to MTI's ANDA being made "in view" of the documents referenced in the allegation and, accordingly, deny the foregoing allegation. To the extent Paragraph 114 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

115. The changes made in the amendment to MTI's ANDA No. 209982 are insubstantial and the products described before the amendment are essentially the same as those described after, such that they do not alter the infringement analysis with respect to any of the '979, '980, '589 or '174 patents.

ANSWER: As more specifically set forth in Plaintiffs' Complaint, the letter purportedly sent on behalf of MTI dated October 27, 2022 represented that MTI was providing the letter to Plaintiffs "based on an ANDA amendment submitted to FDA addressing previous FDA inquiries sent to [MTI]." Specifically, the letter represented that MTI's ANDA amendment "includes changes to the components of [MTI's] ANDA Products." Applicable regulations require that "[a]n amendment to an ANDA is required to contain an appropriate patent certification . . . if approval is sought . . . [t]o make other than minor changes in a product formulation..." 21 C.F.R. § 314.96(d)(1)(iii). On information and belief, the changes made in MTI's ANDA amendment to at least the components of the MTI ANDA Product are substantial. On information and belief, MTI has revised and/or supplemented the ANDA and modified its proposed production and the manufacture thereof. The MTI ANDA Product now proposed in MTI's ANDA following the amendment is not essentially the same as the MTI ANDA Product proposed before the amendment. To the extent Paragraph 115 contains other allegations to which a response is required, Plaintiffs deny any remaining allegations.

116. MTI will be materially prejudiced if Counterclaim Defendants are permitted to maintain allegations of infringement of the '979, '980, '589 and '174 patents in spite of Counterclaims Defendants' prior actions. As a result, Counterclaim Defendants' claims of infringement under the '979, '980, '589 and '174 patents against MTI should be barred based on equitable estoppel.

ANSWER: Denied.

PRAAYER FOR RELIEF

The remainder of MTI's Counterclaims recite a prayer for relief to which no response is required. To the extent a response may be required, Plaintiffs deny that MTI is entitled to any remedy or relief, including those requested.

AFFIRMATIVE DEFENSES

Plaintiffs state the following affirmative defenses in response to MTI's Counterclaims and Prayer for Relief, and reserve their right to assert other and additional affirmative defenses not asserted herein of which they become aware through discovery or other investigation as may be appropriate at a later time. In asserting these defenses, Plaintiffs do not assume any burden of proof, persuasion, or production with respect to any issue where the applicable law places the burden upon MTI.

FIRST AFFIRMATIVE DEFENSE

The Counterclaims, in whole or in part, fail to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The Counterclaims, in whole or in part, fail to allege facts sufficient to state a cause of action to support each count.

THIRD AFFIRMATIVE DEFENSE

The Court lacks subject matter jurisdiction over Counts IX through XII of the Counterclaims, in whole or in part.

FOURTH AFFIRMATIVE DEFENSE

MTI is not entitled to attorneys' fees and costs against Plaintiffs. MTI has not sufficiently alleged and cannot prove that this is an exceptional case in MTI's favor pursuant to 35 U.S.C. § 285. This is not an exceptional case in MTI's favor pursuant to 35 U.S.C. § 285 and, to the contrary, is an exceptional case pursuant to 35 U.S.C. § 285 in Plaintiffs' favor.

FIFTH AFFIRMATIVE DEFENSE

The relief sought by each Counterclaim, and the Counterclaims as a whole, is not available under the legal theories pleaded in each respective Counterclaim.

SIXTH AFFIRMATIVE DEFENSE

The '979, '980, '589 and '174 patents each have valid and enforceable claims and comply with the statutory provisions of Title 35 of the United States Code.

SEVENTH AFFIRMATIVE DEFENSE

MTI's claims for relief are barred, in whole or in part, under principles of equity, including, but not limited to, estoppel, judicial estoppel, collateral estoppel, equitable estoppel, res judicata, forfeiture, laches, waiver, acquiescence, preclusion, inconsistent positions, and/or unclean hands.

EIGHTH AFFIRMATIVE DEFENSE

MTI's Counterclaims are barred, in whole or in part, because MTI lacks standing, injury in fact, causation, and redressability.

NINTH AFFIRMATIVE DEFENSE

MTI is not authorized under the covenant not to sue MTI has identified with respect to the MTI ANDA Product now proposed in MTI's ANDA amendment.

TENTH AFFIRMATIVE DEFENSE

MTI's Counterclaims are barred, in whole or in part, by the *Noerr-Pennington* Doctrine and related authority.

ELEVENTH AFFIRMATIVE DEFENSE

MTI's Counterclaims, in whole or in part and to the extent predicated upon the Declaratory Judgment Act, should be dismissed under the Court's unique and substantial discretion under the Declaratory Judgment Act, *e.g.*, 28 U.S.C. § 2201, to dismiss declaratory judgment claims because judgment on such claims will not serve a useful purpose in clarifying the legal relations at issue and is a less effective means to resolve the dispute than judgment on the claims set forth in Plaintiffs' Complaint.

TWELFTH AFFIRMATIVE DEFENSE

MTI has not suffered any damages and is not entitled to any costs or fees.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs have not knowingly or intentionally waived any applicable defenses, and they reserve the right to assert and rely upon other applicable defenses that may become available or apparent throughout the course of this action and discovery. Plaintiffs reserve the right to amend, or seek to amend, their answer, including their affirmative and other defenses.

ADDITIONAL DEFENSES

Plaintiffs reserve all defenses, at law or equity, which may now exist or in the future be available on discovery and further factual investigation in this case.

RELIEF

WHEREFORE Plaintiffs request the following relief:

- A. A judgment denying all relief sought by MTI;
- B. An order dismissing MTI's Counterclaims with prejudice;
- C. A judgment, order, and/or injunction granting each and every form of relief sought by Plaintiffs in their Complaint;
- D. A finding in Plaintiffs' favor that this case is exceptional, and an award of Plaintiffs' attorneys' fees pursuant to 35 U.S.C. § 285;
- E. An award of costs and expenses to Plaintiffs for defending against MTI's Counterclaims; and
- F. Such further and other relief as this Court deems to be just and proper.

Dated at Burlington, Vermont this 6th day of March 2023.

By: /s/ Ritchie E. Berger

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